

REMARKS

I. Amendments to the Claims

Following entry of this amendment, claims 35-40, 44-52, and 57-59 are pending. Claims 1-34, 41-43, and 53-56 have been cancelled. Claims 35, 38, 51, and 52 are amended herein. Claims 57-59 are added. Support for the amendment to claim 35 is found throughout the application as filed, and, in particular, in claims 14, 15, and 32 of the original application. Support for the amended of claim 38 is found in the first two lines on page 6 of the translated specification. Claims 51 and 52 are amended for reasons of form, and they require no support beyond that already shown for those claims. Support for new claim 57 is found in claim 1 of the original application. Support for new claim 58 is found in claims 1, 29, and 30 of the original application. Support for new claim 59 is found in the paragraph beginning on the third line of page 6.

None of the added or amended claims include new matter. Entry and allowance of all of the new and amended claims are hereby requested.

II. Claim Objections

The Office Action objects to claim 41 as allegedly being of improper dependent form. Claim 41 is cancelled herein, and the objection is moot.

III. Claim Rejections - 35 U.S.C. § 112

Claims 41-43 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Claims 41-43 are cancelled herein, and the rejection is moot.

IV. Claim Rejections - 35 U.S.C. § 102

Claims 35-38, 40, 43-48, 50, 51, and 53-56 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Seed *et al.*, EP 0 580 305 A2. Applicants respectfully disagree. For the claims to be anticipated by Seed, Seed must teach all of the limitations of the claims. Seed does not teach all of the limitations of the amended claims.

Embodiments of the invention provide a method for isolating nucleic acids that allows purification on solid phases without using a washing solution containing components disturbing any following downstream applications. This is done using a combination of solid phases, binding solutions, and washing solutions.

Neither Seed nor any other document discloses a method for isolating nucleic acids from a solution by binding to a solid phase comprising constituents selected from SiO₂ suspensions, aerosols, magnetized silica particles, cut silicic acid, pyrogenous silicic acid, magnetic silica particles, glass fiber fleeces, silica membranes or membranes that carry functional groups that conform to glass fiber fleeces or silica membranes. They further do not report using a washing solution that contains mono- and multivalent cations in weak ionic strength, without alcohol

Any prior use of solid carriers required use of a washing buffer containing alcohol or a washing buffer with high ionic strength to avoid an early elution of the nucleic acids. This results in the necessity of washing steps to remove salt or alcohol components that usually impair downstream applications.

Seed *et al.* does not disclose use of the solid carriers claimed in the present invention without disturbing washing buffer components. To the contrary, Seed *et al.* teaches away from such a use. One of skilled in the art would, upon reviewing Seed *et al.*, assume that mono- and

multivalent cations are interchangeable. Seed *et al.* reports no qualitative difference between mono- and multivalent cations in their binding effect. This is contrary to the present invention, which claims an effective combination of multivalent and monovalent cations for retention of nucleic acids.

Claims 35, 49, and 52 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,898,071, to Hawkins. Hawkins reports the binding of nucleic acids to functionalized surfaces, in particular surfaces of magnetic beads. The functional groups purportedly may be carboxyl groups. This does not mention or affect silica materials. Furthermore, binding of nucleic acids is purportedly transmitted by polyalkylene glycol-polyethylene glycol, and the binding or precipitation of nucleic acids by PEG is improved by dissolution of salt in the respective solution. The salt ions of Hawkins, however, do not provide the central binding role provided by the claimed invention. Furthermore, Hawkins does not report a combination of monovalent and multivalent ions.

Hawkins reports a high salt concentration for the washing buffer solution. Suitable salt concentrations are reportedly greater than about 1.0 mol/liter, and preferably greater than about 5 mol/liter (col. 6, lines 45-46; column 5, lines 61-64; and example 1, column 9, line 66). Washing steps are indispensable to Hawkins, which is contrary to the methods of the present invention, in which salts are used in combinations, salt concentrations may be low, and washing steps may be skipped.

Claims 35 and 39 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 6,274,308, to Lee, *et al.* Lee, *et al.* purportedly uses chaotropic salt mixtures for lyses of their nucleic acids-containing materials. Lee, *et al.* relies on the allegedly unexpected

finding that porous hydrophilic polyvinylidene fluoride (PVDF) membranes specifically and reversibly bind nucleic acids (column 7, lines 26-28; example 1, column 13, line 65 through column 14, line 2. This is different from the instant application, in which non-chaotropic salts are described. The binding is done at silica surfaces and others.

Although Lee, *et al.* may report the addition of silica beads to the sample, it does not do so in combination with a buffer not containing alcohol, or in combination with an ionically weak salt solution not containing alcohol. To the contrary, Lee, *et al.* reports use of washing buffers with alcoholic components. As with Hawkins, these washing steps to remove salts or alcoholic components appear indispensable.

As discussed above, neither Hawkins, nor Lee, nor Seed includes all of the limitations of the amended claims, either alone or in combination. The rejections should be withdrawn, and the claims should be reconsidered and allowed.

CONCLUSION

Applicants believe that the amendments and remarks set forth in this paper place this Application in a condition for allowance, and such action is respectfully requested at an early date. If the Examiner believes that personal communication will expedite the prosecution of this Application, the Examiner is invited to telephone the Applicants' undersigned attorney directly.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Duane A. Stewart III", with a stylized flourish at the end.

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